Docket No.: 231893US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	:	
Christine NOEL, et al.	:	EXAMINER: YU, GINA C.
SERIAL NO.: 10/685,505	:	
FILED: OCTOBER 16, 2003	:	GROUP ART UNIT: 1617

FOR: COMPOSITION IN THE FORM OF AN OIL-IN-WATER EMULSION AND USES THEREOF

APPEAL BRIEF

Appellants submit this brief in response to the Rejection dated September 30, 2010.

REAL PARTY IN INTEREST

The real party in interest herein is L'Oréal S.A. of Paris, France.

RELATED APPEALS AND INTERFERENCES

To the best of Appellants' knowledge, there are no appeals or interferences which will directly affect or be directly affected by, or have a bearing on, the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1, 6, 8-18 and 20 are rejected and on appeal. Claims 21-24 have been withdrawn from consideration. Claims 2-5, 7 and 19 have been canceled.

STATUS OF AMENDMENTS

All amendments and remarks filed in this case have been entered and considered.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1: The invention relates to:

stable compositions in the form of an oil-in-water emulsion comprising an oily phase dispersed in an aqueous phase (specification at page 1, lines 16-19, 25-26 and page 2, lines 1-3)

and a hydrophilic polymer, (specification at page 1, line 19)

said composition further comprising:

(1) at least one elastomeric organopolysiloxane dispersed in the oily phase, wherein the elastomeric organopolysiloxane is present in an amount ranging from 1 to 20% by weight with respect to the total weight of the composition (specification at page 14, lines 21-26)

and is obtained by addition and crosslinking reaction, in the presence of a catalyst, of at least:

- a first organopolysiloxane (i) containing two vinyl groups in α-ω position on the silicone chain per molecule; and
- a second organopolysiloxane (ii) containing at least one hydrogen atom linked to a silicon atom per molecule, (specification at page 13, lines 4-12)

and (2) a glycine derivative selected from the group consisting of capryloylglycine, undecylenoylglycine, and mixtures thereof, (specification at page 10, lines 10-15)

wherein the glycine derivative is present in an amount sufficient to stabilize the composition, (specification at page 1, lines 25-26 and page 2, lines 1-3)

wherein the composition is free of surfactant (original claim 19).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 6, 8-18 and 20 are obvious under 35 U.S.C. § 103 over EP 1,055,406/U.S. patent 6,465,402 ("Lorant") in view of U.S. patent 6,346,255 ("Fontinos").

ARGUMENT

Claims 1, 6, 8-18 and 20 are obvious under 35 U.S.C. § 103 over Lorant in view of Fontinos

The claims as amended are directed to a specific type of composition (oil-in-water emulsion) having (1) at least 1% of a specific elastomeric compound; (2) capryloylglycine and/or undecylenoylglycine; and (3) a hydrophilic polymer, wherein the composition is stable as a result of the glycine derivative which is present in an amount sufficient to effect such stabilization. No stabilizing effective amount of surfactant is present in the invention compositions, meaning that irritation resulting from the presence of surfactant is not associated with the invention compositions. The applied art neither teaches nor suggests such specific, glycine derivative-stabilized, non-irritating emulsions. In particular, the applied art does not disclose -- nor does the Examiner ever assert that the applied art discloses -- the required glycine derivative(s) present in a composition stabilizing effective amount.

As noted in the Background section of the present application, oil-in-water emulsions containing at least 1% elastomeric organopolysiloxane and hydrophilic polymer(s) tend toward destabilization. (See, page 5 of the present application). Appellants have discovered that adding capryloylglycine and/or undecylenoylglycine to oil-in-water emulsions containing at least 1% of a specific type of elastomeric organopolysiloxane and hydrophilic polymer(s) improves stability of the emulsions even in the absence of stabilizing effective amounts of surfactant. For example, examples 3-6 of the present application, demonstrate that emulsions containing the claimed glycine derivatives are stable without surfactant, whereas emulsions lacking the required glycine derivatives are not. Similarly, the Rule 132 declarations submitted July 24, 2007, and November 1, 2006, demonstrate that emulsions containing the claimed glycine derivatives are stable without surfactant, whereas emulsions containing different amino acid compounds (including glycine itself) are not.

The data in both the examples of the present application and the Rule 132 declarations submitted in this case demonstrate that the claimed glycine derivatives can stabilize oil-in-water emulsions containing at least 1% elastomeric organopolysiloxane and hydrophilic polymer(s) without surfactant, and that such stabilization was surprising an unexpected given the instability of and presence of large oily globules in extremely similar compositions. (See, Rule 132 declaration submitted November 1, 2006, at par. 9, and Rule 132 declaration submitted July 24, 2007, at par. 7). Based on this information alone, Appellants respectfully submit that the pending rejections are improper and should be withdrawn.

That is, even assuming that a *prima facie* case of obviousness has been set forth (which, as explained below, is not the case), Appellants have rebutted such a hypothetical case of obviousness with their showing of unexpected and surprising stability of the claimed oil-in-water emulsions.

This is particularly true for claims 12-14 which are directed to specific hydrophilic polymers.

At any rate, no *prima facie* case of obviousness has been set forth. Of particular note in this regard is the fact that none of the applied art recognizes that the required glycine compounds are result effective compounds when added to emulsions containing a significant amount of elastomer -- none of the asserted art teaches, suggests or recognizes that the required glycine derivatives can be added in an amount sufficient to stabilize an elastomer-containing emulsion without the presence of stabilizing effective amounts of surfactant.

Rather, the applied art generally suggests that such glycine derivatives could optionally be added to compositions for some other purpose, if desired, and that other compounds must be added in stabilizing effective amounts. Nowhere is there even a scintilla of a suggestion that the required glycine derivatives could be added to an emulsion containing a significant amount of elastomer, and that the result would be a stable composition without surfactant. The applied art neither teaches, suggests, nor recognizes that adding the required glycine derivatives is a result effective variable with respect to stabilizing elastomer-containing emulsions, particularly emulsions without surfactant. Because of this, no motivation would have existed to add the required glycine

derivatives to the claimed surfactant-less compositions, let alone to add the required glycine derivatives to the claimed compositions and then to optimize their concentration to effect composition stabilization without stabilizing effective amounts of surfactant also being present. Nothing in the applied art would lead one skilled in the art to this invention.

Lorant neither teaches nor suggests the presence of the required glycines. The Examiner recognized this fatal deficiency. (See, Office Action at page 4).

The secondary reference, Fontinos, does not compensate for Lorant's deficiencies. Fontinos neither teaches, suggests, nor recognizes the result effective nature of the claimed glycine derivatives with respect to stabilizing elastomer-containing emulsions -- Fontinos is silent concerning stabilizing elastomer-containing emulsions with the claimed glycine derivatives. Rather, Fontinos describes the required compounds as merely optional, insignificant ingredients. Nothing in Fontinos would lead one of ordinary skill in the art to the importance, significance and result effective nature of the claimed glycine derivatives as required by the claims. The asserted art does not render the claimed invention obvious.

The applied art does not disclose the presence of **a stabilizing effective amount** of the required glycine derivative. For such a disclosure to exist, the applied art would have to disclose or suggest actually stabilizing an elastomer-containing, surfactant-less emulsion. *See, Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 67 U.S.P.Q.2d 1191 (Fed. Cir. 2003)("effective amounts" are not necessarily disclosed by prior art compositions containing the claimed active ingredient; the desired effect must be

achieved). Merely because Fotinos suggests that glycine derivatives can be added as active agents does not mean that it discloses or suggests stabilizing elastomer-containing, surfactant-less emulsions. *See, Abbott Laboratories.*

Further, nothing would have motivated one of ordinary skill in the art to combine the asserted references with the expectation that a stable, acceptable emulsion without surfactant would result. Fontinos relates to a patch or pad. Nothing in either of the applied references would lead one skilled in the art to add an emulsion stabilizing effective amount of the required glycine compound to Lorant's compositions, particularly compositions without stabilizing effective amounts of surfactant. That is, given that Fontinos' patches or pads are so structurally different from Lorant's compositions, no teaching, suggestion or motivation would have existed to add an emulsion stabilizing effective amount of the claimed glycine compounds to Lorant's compositions with the expectation that a stable emulsion would result.

In short, the applied art would not have led one of ordinary skill in the art to optimize the required glycine derivative ingredients in such a way as to produce stable emulsions which contain a significant amount of elastomer and a hydrophilic polymer.

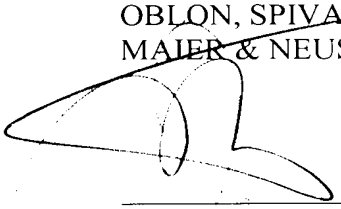
Accordingly, and for at least the above reasons, no *prima facie* case of obviousness exists in the present case.

CONCLUSION

In view of the above remarks and reasons explaining the patentable distinctness of the presently appealed claims over the applied art, Appellants request that the Examiner's rejections all be REVERSED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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APPENDIX I (CLAIMS)

1. (Previously Presented): A stable composition in the form of an oil-in-water emulsion comprising an oily phase dispersed in an aqueous phase and a hydrophilic polymer, said composition further comprising:

(1) at least one elastomeric organopolysiloxane dispersed in the oily phase, wherein the elastomeric organopolysiloxane is present in an amount ranging from 1 to 20% by weight with respect to the total weight of the composition and is obtained by addition and crosslinking reaction, in the presence of a catalyst, of at least:

- a first organopolysiloxane (i) containing two vinyl groups in α-ω position on the silicone chain per molecule; and
- a second organopolysiloxane (ii) containing at least one hydrogen atom linked to a silicon atom per molecule, and

(2) a glycine derivative selected from the group consisting of capryloylglycine, undecylenoylglycine, and mixtures thereof, wherein the glycine derivative is present in an amount sufficient to stabilize the composition, wherein the composition is free of surfactant.

6. (Original): The composition according to Claim 1, wherein the amount of lipophilic compound(s) is 0.01% to 20% by weight relative to the total weight of the composition.

8. (Previously Presented): Composition according to Claim 1, wherein the first organopolysiloxane (i) is an α,ω-dimethylvinylpolydimethylsiloxane.

9. (Original): The composition according to Claim 1, wherein the organopolysiloxane is in a gel obtained according to the following steps:

- (a) mixing of first and second organopolysiloxanes (i) and (ii);
- (b) adding an oily phase to the mixture from step (a);
- (c) polymerizing the first and second organopolysiloxanes (i) and (ii) in the oily phase in the presence of a platinum catalyst.

10. (Previously Presented): The composition according to Claim 1, wherein the amount of elastomeric organopolysiloxane(s) is 5% to 20% by weight relative to the total weight of the composition.

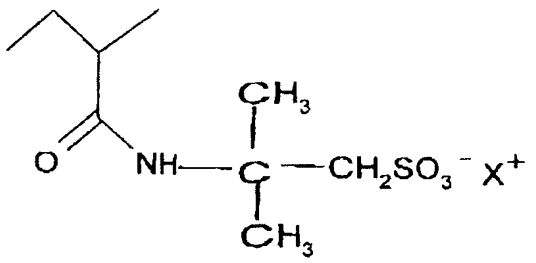
11. (Original): The composition according to Claim 1, wherein the hydrophilic polymer is selected from the group consisting of carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers, and mixtures thereof.

12. (Original): The composition according to Claim 1, wherein the hydrophilic polymer is a poly(meth)acrylamido(C_1-C_4)alkylsulphonic acid.

13. (Original): The composition according to Claim 12, wherein the poly(meth)acrylamido(C_1-C_4)alkylsulphonic acid is crosslinked and at least 90% neutralized.

14. (Original): The composition according to Claim 12, wherein the poly(meth)acrylamido(C_1-C_4)alkylsulphonic acid is a polyacrylamidomethylpropane-sulphonic acid comprising, randomly distributed:

a) from 90% to 99.9% by weight of units of formula (IV) below:



(IV)

in which X^+ denotes a cation or a mixture of cations, including H^+,

b) from 0.01% to 10% by weight of at least one crosslinking unit comprising at least two olefinic double bonds,

the weight proportions of a) and b) being defined relative to the total weight of the polymer.

15. (Original): The composition according to Claim 14, wherein the polyacrylamidomethylpropanesulphonic acid comprises from 98% to 99.5% by weight of units of formula (IV) and from 0.2% to 2% by weight of crosslinking units.

16. (Original): The composition according to Claim 1, wherein the amount of hydrophilic polymer is 0.1% to 10% by weight relative to the total weight of the composition.

17. (Original): The composition according to Claim 1, wherein the amount of oily phase is 1% to 50% by weight relative to the total weight of the composition.

18. (Original): The composition according to Claim 1, wherein the oily phase comprises at least one volatile oil.

20. (Original): The composition according to Claim 1, in the form of a cosmetic or dermatological composition.

APPENDIX II (EVIDENCE)

1. Rule 132 declaration submitted July 24, 2007.

2. Rule 132 declaration submitted November 1, 2006.

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IN RE APPLICATION OF: :

Christine NOEL, et al. : EXAMINER: S. GOLLAMUDI

SERIAL NO.: 10/685,505 :

FILED: OCTOBER 16, 2003 : GROUP ART UNIT: 1616

FOR: COMPOSITION IN THE FORM OF AN OIL-IN-WATER EMULSION AND USES THEREOF

DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

I, Ann-France RATEL (formerly Anne-France LIVERNETTE), hereby declare:

1. I am a named inventor on the above-identified patent application, and am employed by L'ORÉAL as an engineer. I have experience in the field of preparing and analyzing cosmetic and/or dermatological compositions, particularly emulsions.

2. The following observations and experiments were carried out by me or under my direct supervision and control.

3. The following compositions were prepared:

Ingredient	Invention composition	Comparative Example	Base Composition
Hostacerin AMPS (sold by Hoescht)	2%	2%	2%

Demineralized water	Qs 100%	Qs 100%	Qs 100%
Cyclopentasiloxane	6%	6%	6%
KSG 16 (containing 24% active material)	15%	15%	15%
Undecylenoylglycine	0.125%	___	___
Methionine	___	0.125%	___
Preservative	0.4%	0.4%	0.4%
Coloring solution 0.1%	0.8%	0.8%	0.8%
triethanolamine	0.097%	___	___

4. Invention Composition was identical to Comparative Example except that Comparative Example contained methionine. In contrast, Invention Composition contained undecylenoylglycine and a small amount of triethanolamine (to help with solubilization). No help with solubilization was necessary for Comparative Example, so no triethanolamine was added. Base Composition did not contain methionine or undecylenoylglycine.

5. Comparative Composition which contained methionine, and Base Composition which did not contain any amino acid, were unstable, meaning among other things that these compositions were unacceptable for commercial use. That is, these two compositions were unstable dispersions having large oily globules throughout as demonstrated by photograph II (Comparative Example) and photograph III (Base Composition) attached hereto at Tab A. Such large oily globules are characteristic of unstable compositions.

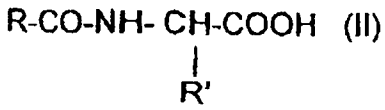
6. In stark contrast, Invention Composition was a stable cream composition. It was a fine dispersion and did not contain large oily globules. (See, photograph I at Tab A).

7. Given the similarity of Invention Composition, Comparative Example and Base Composition, it was surprising and unexpected that compositions containing a lipophilic amino acid were stable, whereas identical compositions lacking any amino acid or containing methionine were not stable.

8. Such surprising and unexpected results are fully representative of the present invention. That is, I would expect compositions in the form of an oil-in-water emulsion comprising an oily phase dispersed in an aqueous phase and a hydrophilic polymer, said composition further comprising:

(1) at least one elastomeric organopolysiloxane, and

(2) an emulsion stabilizing effective amount of at least one glycine derivative of formula (II) below or a salt of such a compound:



in which R is selected from the group consisting of alkyl and alkenyl radicals containing from 6 to 22 carbon atoms and R' is hydrogen or an alkyl radical containing from 1 to 30 carbon atoms, to possess improved stability properties like those of Invention Composition. I have no reason to expect otherwise.

9. The fact that the compositions of the present invention are more stable is commercially significant. More stable products are more desirable to consumers and, thus, more commercially viable. Also, active ingredients in more stable products are more likely to maintain activity longer than in unstable products, making such stable products more desirable to consumers.

10. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

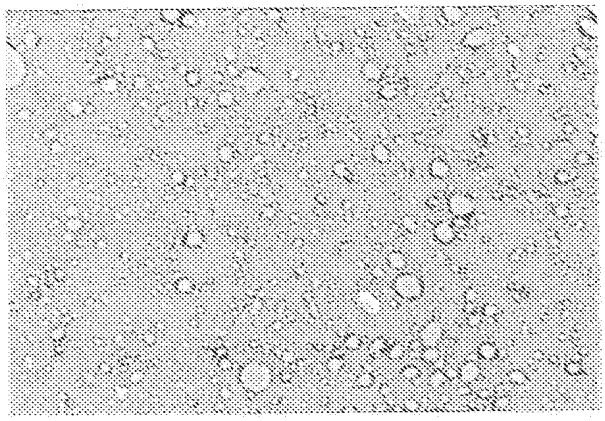
11. Further deponent sayeth not.

AF. RATEL
Name

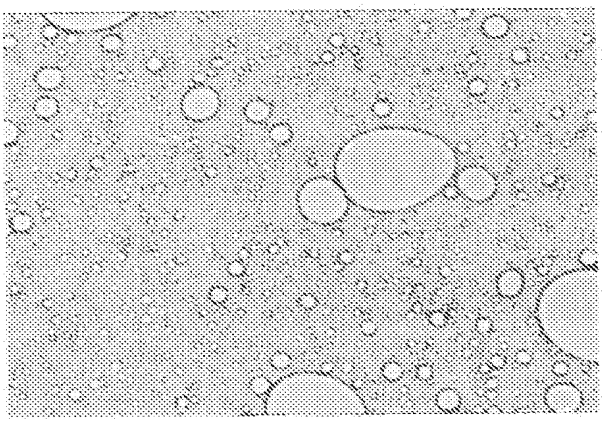
Ratelaf
Signature

19/07/07
Date

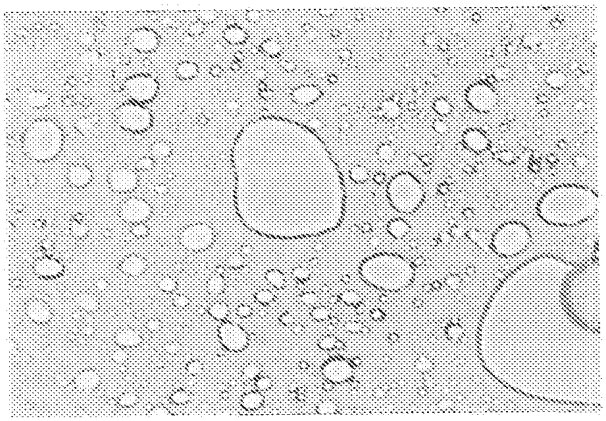
TAB A



Example of the invention
(0.5% KOH)



Comparative example
(0.5% KOH)



Base (0.5% KOH)

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SIR:

I, Ann-France RATEL (formerly Anne-France LIVERNETTE), hereby declare:

1. I am a named inventor on the above-identified patent application, and am employed by L'ORÉAL as a chemist. I have experience in the field of preparing and analyzing cosmetic and/or dermatological compositions, particularly emulsions.

2. The following observations and experiments were carried out by me or under my direct supervision and control.

3. The following six compositions were prepared:

Ingredient	Invention composition 1B	Comparative Example 1	Comparative Example 1A
Hostacerin AMPS (sold by Hoescht)	2%	2%	2%

Demineralized water	Qs 100%	Qs 100%	Qs 100%
Cyclopentasiloxane	6%	6%	6%
KSG 16 (containing 24% active material)	5%	5%	5%
Undecylenolyglycine	0.125%	—	—
Glycine	—	—	0.125%

Ingredient	Invention composition 2B	Comparative Example 2	Comparative Example 2A
Hostacerin AMPS (sold by Hoescht)	2%	2%	2%
Demineralized water	Qs 100%	Qs 100%	Qs 100%
Cyclopentasiloxane	6%	6%	6%
KSG 16 (containing 24% active material)	15%	15%	15%
Undecylenolyglycine	0.125%	—	—
Glycine	—	—	0.125%

4. Invention Composition 1B was identical to Comparative Example 1 except that Comparative Example 1 did not contain a lipophilic amino acid. Invention Composition 1B was also identical to Comparative Composition 1A except that Comparative Composition 1A contained a non-lipophilic amino acid (glycine) instead of a lipophilic amino acid.

5. Similarly, Invention Composition 2B was identical to Comparative Example 2 except that Comparative Example 2 did not contain a lipophilic amino acid. Invention

Composition 2B was also identical to Comparative Composition 2A except that Comparative Composition 2A contained a non-lipophilic amino acid (glycine) instead of a lipophilic amino acid.

6. Comparative Compositions 1 and 2 which did not contain any amino acid, lipophilic or non-lipophilic, were unstable compositions. That is, these two compositions were unstable dispersions having large oily globules throughout. Such large oily globules are characteristic of unstable compositions.

7. Comparative Compositions 1A and 2A which contained a non-lipophilic amino acid were also unstable compositions. That is, these two compositions were also unstable dispersions having large oily globules throughout. Thus, both compositions having no amino acid (comparative compositions 1 and 2) and compositions containing a non-lipophilic amino acid (comparative compositions 1A and 2A) were unstable, meaning among other things that these compositions were unacceptable for commercial use.

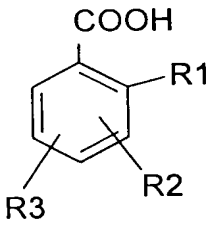
8. In stark contrast, Invention Composition 1B and 2B were stable, cream compositions. They were fine dispersions and did not contain large oily globules.

9. Given the similarity of Compositions 1, 1A and 1B, and Compositions 2, 2A and 2B, it was surprising and unexpected that compositions containing a lipophilic amino acid were stable, whereas identical compositions lacking a lipophilic amino acid were not stable.

10. Such surprising and unexpected results are fully representative of the present invention. That is, I would expect compositions in the form of an oil-in-water emulsion comprising an oily phase dispersed in an aqueous phase and a hydrophilic polymer, said composition further comprising:

(1) at least one elastomeric organopolysiloxane, and

(2) at least one lipophilic compound selected from the group consisting of lipophilic amino acid compounds, salts thereof, lipophilic salicylic acid compounds of formula (I) below, and salts thereof:



(I)

in which:

- R_1 represents a hydroxyl radical or an ester of formula:

-O-CO-R_4

in which R_4 is a saturated or unsaturated aliphatic radical containing from 1 to 26 carbon atoms, an amine or thiol function optionally substituted with an alkyl radical containing from 1 to 18 carbon atoms,

- R_2 and R_3, independently of each other, are in position 3, 4, 5 or 6 on the benzene ring and represent, independently of each other, a hydrogen atom or a radical:

$-(O)_n-(CO)_m-R_5$

in which n and m, independently of each other, are each an integer equal to 0 or 1; provided that R_2 and R_3 are not simultaneously hydrogen atoms;

- R_5 represents a hydrogen, a linear, branched or cyclized saturated aliphatic radical containing from 1 to 18 carbon atoms, an unsaturated radical containing from 3 to 18 carbon atoms, bearing one to nine conjugated or non-conjugated double bonds, the radicals optionally being substituted with at least one substituent chosen from halogen atoms, trifluoromethyl radicals, hydroxyl in free form or esterified with an acid containing from 1 to 6 carbon atoms, or carboxyl in free form or esterified with a lower alcohol containing from 1

to 6 carbon atoms, or an aromatic radical containing from 6 to 10 carbon atoms, to possess improved stability properties like those of Invention Compositions 1B and 2B. I have no reason to expect otherwise.

11. The fact that the compositions of the present invention are more stable is commercially significant. More stable products are more desirable to consumers and, thus, more commercially viable. Also, active ingredients in more stable products are more likely to maintain activity longer than in unstable products, making such stable products more desirable to consumers.

12. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

13. Further deponent sayeth not.

PATEL Anne-France
Name

Signature

18/10/06.
Date

APPENDIX III (RELATED PROCEEDINGS)

None.